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AF/1617

ABB1130P0901US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ) NOVEL FORMULATIONS COMPRISING  
J. Patel et al. ) LIPID-REGULATING AGENTS  
Serial Number: 09/524,113 )  
Filed: March 13, 2000 ) Group Art Unit: 1617  
 )  
 ) Examiner: Mojdeh Bahar

TRANSMITTAL OF REPLY BRIEF

Commissioner of Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed herewith is the Reply Brief with regard to the above-referenced patent application (being filed in triplicate).

If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account No. 23-0785.

Respectfully submitted,

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER

By: Martin L. Katz  
Martin L. Katz, Reg. No. 29,011

Date: March 15, 2004

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37 CFR 1.8  
CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service, as first class mail in an envelope addressed to: Commissioner of Patents, P. O. Box 1450, Alexandria, Virginia 22313-1450 on March 15, 2004.

A handwritten signature in cursive script, reading "Rebecca J. Willis". The signature is written in black ink and is positioned above a horizontal line.

Rebecca J. Willis



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

|                       |  |
|-----------------------|--|
| In re Application of: | ) Novel Formulations Comprising Lipid- |
|                       | ) Regulating Agents                    |
| J. Patel et al.       | )                                      |
|                       | ) Group Art Unit: 1617                 |
| Serial No. 09/524,113 | )                                      |
|                       | ) Examiner: Mojdeh Bahar               |
| Filed: March 13, 2000 | )                                      |

REPLY BRIEF

Commissioner for Patents  
P. O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In response to the Examiner's Answer dated January 14, 2004 issued in the  
present application, this is the Appellants' Reply Brief.

**Reply to Grounds of Rejection**

The Examiner's Answer states, "Appellant's arguments have been fully considered but they are not persuasive. Appellant first argues that Lacy does not render the claims unpatentable because Lacy requires surfactants that are different in character than the specifically claimed emulsifiers herein. Note that Lacy enumerates certain hydrophilic surfactants that are particularly claimed herein, e.g., phospholipids, poly[oxy]ethylene sorbitan fatty acid derivatives, castor oil or hydrogenated [ester] castor oil ethoxylates, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers and block co-polymers (see instant claims 19, 1, 7). Note also that the lipophilic surfactant, e.g., propylene glycol, taught by Lacy is also claimed herein (see the instant claim 12). Therefore both the hydrophilic and the lipophilic surfactants of Lacy read on the instant claims."

While the Examiner's Answer correctly states that Lacy et al. enumerate certain hydrophilic surfactants as stated above. It is important to note that these surfactants represent only part of Lacy's disclosed surfactant system - the hydrophilic surfactant component.

As pointed out in the Appeal Brief, Lacy et al. teaches a carrier system for a hydrophobic drug comprising (a) a digestible oil and (b) a pharmaceutically acceptable surfactant comprising a hydrophilic surfactant component and a lipophilic surfactant

component. Lacy et al. describe the surfactant as being capable of "dispersing" the oil in vivo upon administration, said surfactant comprising a hydrophilic surfactant component, and being such that it does not substantially inhibit the lipolysis of the oil. Lacy et al., in a preferred aspect, still further describes the surfactant as comprising a hydrophilic surfactant component which substantially inhibits the in vivo lipolysis of a digestible oil and a lipophilic surfactant component capable of at least substantially reducing said inhibitory effect of said hydrophilic surfactant component (column 3, lines 38-67).

The present invention, provides a composition **consisting essentially of** a fibrate dissolved in at least one oil with one selected emulsifier, and being such that the emulsifier does not exhibit or demonstrate the property of "not substantially inhibiting the lipolysis of the oil." The emulsifier does not contain a hydrophilic surfactant component that substantially inhibits the in vivo lipolysis of an oil, and a lipophilic surfactant component capable of at least substantially reducing said inhibitory effect of said hydrophilic surfactant component. Fibrates are simply dissolved in at least one oil with one selected emulsifier; there is not the requirement for a surfactant that does not substantially inhibit lipolysis. The inclusion of a surfactant that does not substantially inhibit lipolysis of an oil is an important property of Lacy et al. compositions (column 3, lines 38-45 and claim 1); this is not a property of the presently claimed invention.

The Examiner's Answer further notes that the lipophilic surfactant, e.g., propylene glycol, taught by Lacy et al. is also claimed herein. However, Lacy et al. do not teach

propylene glycol as a lipophilic surfactant, but as an example hydrophilic solvent (col. 13, lines 49-55). Thus, the argument that both the hydrophilic and lipophilic surfactants of Lacy et al. read on the instant claims is incorrect; therefore, Lacy et al. clearly teaches away from the instant composition.

For the above-noted reasons and those set forth in the Appeal Brief, the rejection of claims 1, 3, 7-12 and 19 under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. is improper and should be reversed.

Respectfully Submitted,

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER

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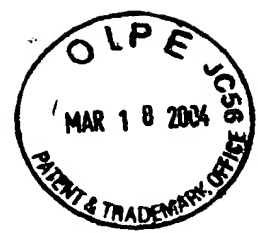



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